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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,927	08/29/2003	Mark E. Gurney	29915/6280N3	3518

4743 7590 09/28/2006

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/652,927	GURNEY ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-11 and 16-19* is/are pending in the application.

4a) Of the above claim(s) *6-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3,4,6-11 and 16-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/05/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignments A and B*.

DETAILED ACTION

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Gregory S. Emch, Art Unit 1649.

Election/Restrictions

Applicants' election with traverse of Group I, claims 1, 3, 4 and 19, in the reply filed on 28 August 2006 is acknowledged. Furthermore, claims 3, 4 and 6 have been amended and claims 2, 5, 12-15 and 20 have been canceled as requested in said reply. Also in the reply, Applicants assert that the restriction requirement between groups I and VIII is improper and should be withdrawn since Group VIII is drawn to a human aspartyl protease containing a valine which corresponds to position 130 of SEQ ID NO: 4 and Group I is drawn to a polypeptide of SEQ ID NO: 4. In addition, Applicants request that, if the product claims of Group I are allowed, the method claims of Group V be rejoined and that to facilitate efficient examination, Applicants request that the restriction requirement between Groups I and V be withdrawn.

Applicants' arguments have been fully considered and are found partially persuasive. The Examiner concedes that Groups I and VIII are not patentably distinct; thus, the restriction requirement between said Groups I and VIII only is hereby withdrawn.

Regarding restriction between Groups I and V, Applicants' arguments are not found persuasive since MPEP § 821.04(b) states, "Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained." As set forth below in the instant office action, the product claims are not allowable. Hence, the Restriction requirement between the remaining Groups is still deemed proper and is therefore made FINAL.

Claims 6-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter, there being no allowable generic or linking claim.

Claims 1, 3, 4 and 16-19 are under examination in the instant office action.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 05 April 2004 is enclosed in this action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4 and 16-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,913,918. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '918 patent is directed to a purified or isolated polypeptide comprising an amino acid sequence at least 95% identical to the aspartyl protease amino acid sequence set forth in SEQ ID NO: 4 and fragments and variants thereof, wherein the fragment is a contiguous fragment that includes aspartyl protease active site tripeptides DTG and DSG and exhibits aspartyl protease activity involved in processing amyloid precursor protein (APP) into amyloid beta, with and

without conservative substitutions. Further, claims 2, 4 and 6 of the '918 patent recite a heterologous tag, as in the instant claim 3. Also, claims 3 and 7 of the '918 patent recites the polypeptide lacking a transmembrane domain, as in the instant claim 4.

Claims 1, 3, 4 and 16-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,825,023. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '023 patent are directed to a purified or isolated polypeptide comprising an amino acid sequence at least 95% identical to a fragment of the aspartyl protease amino acid sequence set forth in SEQ ID NO: 4, wherein the fragment is a contiguous fragment that includes aspartyl protease active site tripeptides DTG and DSG and exhibits aspartyl protease activity involved in processing amyloid precursor protein (APP) into amyloid beta, wherein said polypeptide lacks a transmembrane domain. Further, claim 2 of the '023 patent recites a heterologous tag, as in the instant claim 3.

Claims 1, 3, 4 and 16-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,828,117. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '117 patent are directed to an isolated and purified polypeptide comprising the amino acid sequence set forth in SEQ

ID NO: 4, and functional fragments thereof, wherein the fragment comprises the active site tripeptides DTG and DSG.

Claims 1, 3, 4 and 16-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending application No. 10/652,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-4 of the '830 application are directed to a purified or isolated polypeptide an amino acid sequence at least 90% identical to a fragment of the aspartyl protease amino acid sequence set forth in SEQ ID NO: 4; wherein the fragment includes the aspartyl protease active site tripeptides DTG and DSG and exhibits Asp2 aspartyl protease activity involved in processing APP into amyloid beta, wherein substitution differences between the polypeptide and fragment are conservative. Also, claim 3 of the '830 application recites the polypeptide lacking a transmembrane domain, as in the instant claim 4. Further, claim 4 of the '830 application recites a heterologous tag, as in the instant claim 3.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3, 4 and 16-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 151-156 and 159-163 of copending Application No. 10/940,867. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 151-156

and 159-163 of the '867 application are directed to a purified polypeptide Asp2 polypeptide (including SEQ ID NO: 4) which cleaves mammalian APP, or a fragment, analog, or derivative thereof that retains the APP cleaving ability. Also, claims 155 and 159 of the '867 application recite the polypeptide lacking a transmembrane domain, as in the instant claim 4. Further, claim 160 of the '867 application recites a heterologous tag, as in the instant claim 3.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants' listing of related pending U.S. patent applications included with the IDS filed 05 April 2004 is acknowledged and appreciated. It is requested that Applicants' provide the Examiner with an updated listing if the Examiner has overlooked any related subject matter that has not been addressed in the double patenting rejections set forth above.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 1, 3 and 4 are directed to a purified or isolated polypeptide that comprises an amino acid sequence selected from the group consisting of: (a) the amino acid sequence set forth in SEQ ID NO: 4; (b) a fragment of (a) that exhibits aspartyl protease activity involved in processing APP into amyloid beta and includes aspartyl protease active site tripeptides DTG and DSG; (c) a conservative substitution variant of (a) or (b), wherein the conservative substitution variant comprises an amino acid sequence encoded by a nucleic acid molecule that hybridizes under the following stringent hybridization conditions to the complement of SEQ ID NO: 3: (1) hybridization at 42°C in a hybridization buffer comprising 6x SSC and 0.1% SDS, and (2) washing at 65°C in a wash solution comprising 1x SSC and 0.1% SDS; wherein the conservative substitution variant exhibits aspartyl protease activity involved in processing APP into amyloid beta. Claims 16-19 are directed to an isolated biologically active human aspartyl protease containing a valine at a position which corresponds to position 130 of SEQ ID NO: 4.

The specification at p.30 teaches that variants and derivatives, including fragments, of Hu-Asp proteins having the native amino acid sequences given in SEQ ID NOs: 2, 4, and 6 that retain any of the biological activities of Hu-Asp are encompassed by the present invention. Fragments of Hu-Asp include those that contain the active site

domain containing the amino acid sequence DTG, fragments that contain the active site domain amino acid sequence DSG, fragments containing both the DTG and DSG active site sequences, fragments in which the spacing of the DTG and DSG active site sequences has been lengthened and fragments in which the spacing has been shortened. Examples include: fragments of Hu-Asp in which the transmembrane domain has been removed to allow production of Hu-Asp2 in a soluble form, and peptides of the two halves of Hu-Asp2, each containing a single active site DTG or DSG sequence that can be produced independently as recombinant polypeptides and then combined in solution where they reconstitute an active protease. Further variants are contemplated at pp.31-33 and include: 6 polypeptide variants that recite specific sequences of SEQ ID NO: 4.

Claims 1, 3, 4 and 16-19 are genus claims because the specification (and claims) do not set forth the structure of the multitude of fragments and variants that are encompassed by the invention. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Because the genus is highly variant, any fragment that exhibits aspartyl protease activity or any isolated biologically active protease containing a valine at a position which corresponds to position 130 of SEQ ID NO: 4 is insufficient to describe the genus. One of skill in the art would reasonably

conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus.

Claims 1, 3, 4 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some Hu-Asp fragments and variants does not reasonably provide enablement for any Hu-Asp fragment and/or variant comprising any fragment of SEQ ID NO: 4 that exhibits aspartyl protease activity involved in processing APP into amyloid beta and includes aspartyl protease active site tripeptides DTG and DSG, or any conservative substitution variant of SEQ ID NO: 4 or of any fragment of SEQ ID NO: 4, wherein the conservative substitution variant comprises an amino acid sequence encoded by a nucleic acid molecule that hybridizes under the disclosed stringent hybridization conditions to the complement of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

Claims 1, 3 and 4 are directed to a purified or isolated polypeptide that comprises an amino acid sequence selected from the group consisting of: (a) the amino acid sequence set forth in SEQ ID NO: 4; (b) a fragment of (a) that exhibits aspartyl protease activity involved in processing APP into amyloid beta and includes aspartyl protease active site tripeptides DTG and DSG; (c) a conservative substitution variant of (a) or (b), wherein the conservative substitution variant comprises an amino acid sequence encoded by a nucleic acid molecule that hybridizes under the following stringent hybridization conditions to the complement of SEQ ID NO: 3: (1) hybridization at 42°C in a hybridization buffer comprising 6x SSC and 0.1% SDS, and (2) washing at 65°C in a wash solution comprising 1x SSC and 0.1% SDS; wherein the conservative substitution variant exhibits aspartyl protease activity involved in processing APP into amyloid beta. Claims 16-19 are directed to an isolated biologically active human aspartyl protease containing a valine at a position which corresponds to position 130 of SEQ ID NO: 4.

The specification at p.30 teaches that variants and derivatives, including fragments, of Hu-Asp proteins having the native amino acid sequences given in SEQ ID NOs: 2, 4, and 6 that retain any of the biological activities of Hu-Asp are encompassed by the present invention. Fragments of Hu-Asp include those that contain the active site domain containing the amino acid sequence DTG, fragments that contain the active site domain amino acid sequence DSG, fragments containing both the DTG and DSG active site sequences, fragments in which the spacing of the DTG and DSG active site sequences has been lengthened, fragments in which the spacing has been shortened. Examples include fragments of Hu-Asp in which the transmembrane domain has been

removed to allow production of Hu-Asp2 in a soluble form and peptides of the two halves of Hu-Asp2, each containing a single active site DTG or DSG sequence that can be produced independently as recombinant polypeptides and then combined in solution where they reconstitute an active protease. Further variants are contemplated at pp.31-33 and include: 6 polypeptide variants that recite specific sequences of SEQ ID NO: 4.

Claims 1, 3, 4 and 16-19 require the use of a broad genus of polypeptides (i.e., Hu-Asp fragments and variants), and as stated above, Applicants have not described all of the common features of the genus such that the skilled artisan could identify individual members. Furthermore, the potential amino acid sequences encompassed by the claims have particular structures, the predictability of which is complex and outside the realm of routine experimentation. Since detailed information regarding the structural requirements of the multitude of potential amino acid sequences encompassed by the claims are lacking, and given the lack of working examples reciting any and all of said sequences, it is unpredictable as to which variations, if any, meet the limitations of the claims. Although some of the claimed polypeptides must contain the active sites DTG and/or DSG and the polypeptides must exhibit aspartyl protease activity, the claims still encompass an enormous amount of polypeptides. Thus, making said polypeptides and testing them for the claimed biological activity would constitute undue experimentation.

Accordingly, it is well known in the art that even two polypeptides differing in structure by only one amino acid residue can have completely different functions. For example, Mickle et al. (Med Clin North Am. 2000 May; 84(3): 597-607) teaches that

cystic fibrosis (CF) is an autosomal recessive disorder caused by abnormal function of a chloride channel, referred to as the cystic fibrosis transmembrane conductance regulator (CTFR) (p.597). In this polypeptide channel, a mutation of a single glycine to aspartic acid at position 551, gives rise to the CF phenotype. Also, a single phenylalanine deletion at position 508 gives rise to the CF phenotype, thus showing that even the substitution or deletion of a single amino acid in the entire 1480 amino acid CFTR protein sequence can have dramatic and unpredictable effects on the function of the protein.

Additionally, it is known in the art that even a single amino acid change in a protein's sequence can drastically affect the structure of the protein and thus the architecture of an entire cell. For example, Voet et al. (Biochemistry. 1990. John Wiley & Sons, Inc. 126-129 and 228-234) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pp.126-128, section 6-3A and page 230, column 2, first paragraph). Also, Yan et al. (Science 290: 523-527, 2000) teaches that in certain cases, a change of two-amino acid residues in a protein results in switching the binding of the protein from one receptor to another. Thus, as outlined *supra*, the predictability of amino acid sequences that would function as claimed is complex and outside the realm of routine experimentation.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. Due to the large quantity of experimentation necessary to make and use the Hu-Asp polypeptides comprising the plurality of amino acid sequences encompassed by the claims, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the claimed methods, and the breadth of the claims which encompass variant proteins, undue experimentation would be required of the skilled artisan to practice the invention as broadly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,319,689 to Powell et al (document A39 from Applicants' IDS dated 12 April 2004) and as evidenced by Vassar (Adv Drug Deliv Rev. 2002 Dec 7;54(12):1589-602).

Claims 1, 3 and 4 are directed to a purified or isolated polypeptide that comprises an amino acid sequence selected from the group consisting of: (a) the amino acid sequence set forth in SEQ ID NO: 4; (b) a fragment of (a) that exhibits aspartyl protease activity involved in processing APP into amyloid beta and includes aspartyl protease active site tripeptides DTG and DSG; (c) a conservative substitution variant of (a) or (b), wherein the conservative substitution variant comprises an amino acid sequence encoded by a nucleic acid molecule that hybridizes under the following stringent hybridization conditions to the complement of SEQ ID NO: 3: (1) hybridization at 42°C in a hybridization buffer comprising 6x SSC and 0.1% SDS, and (2) washing at 65°C in a wash solution comprising 1x SSC and 0.1% SDS; wherein the conservative substitution variant exhibits aspartyl protease activity involved in processing APP into amyloid beta. Claim 19 is directed to an isolated polypeptide with aspartyl protease activity comprising an amino acid sequence which is identical across its length to a sequence in SEQ ID NO: 4.

The Powell et al. patent discloses an isolated polynucleotide that is 98.2% identical to Applicants' SEQ ID NO: 3 (see attached sequence alignment A and claims 1 and 2), which encodes an aspartyl protease polypeptide (ASP2) that is 99.8% identical to Applicants' SEQ ID NO: 4 with one non-conservative mismatch (see sequence alignment B). The patent also teaches fragments of the polypeptide that retain aspartyl protease activity (col.5, line 54 – col.6, line 35) and variants with conservative and non-conservative substitutions that also retain aspartyl protease activity (col.5, lines 1-9 and 29-46). Further, the patent discloses complements to the polynucleotide (col.1, lines

65-67 and claim 10) and teaches hybridization of nucleic acid molecules to the polynucleotides and complements thereof (col.6, line 63 – col.7, line 2 and col.13, lines 16-65). It is noted that although the Powell et al. patent teaches slightly different stringent conditions for hybridization, the disclosed polynucleotide(s) would have the inherent property of hybridizing to the complement of SEQ ID NO: 3 under the conditions recited by the instant claim 1. Furthermore, although the Powell et al. patent did not expressly teach the claimed function of ASP2 in processing APP into amyloid beta, this is an inherent property of the polypeptides of the patent as evidence by the Vassar reference (entire document, e.g. Abstract). Hence, the teachings of the Powell et al. patent meet the limitations of the instant claims 1 and 19 (i.e., a fragment or a sequence identical to a sequence of SEQ ID NO: 4).

Furthermore, the reference also teaches a heterologous tag (col.9, line 50 – col.10, line 45), thus meeting the limitations of claim 3. The reference teaches soluble fragments of the ASP2 polypeptide (col.20, line 25), thus meeting the limitations of claim 4 (i.e., wherein the polypeptide lacks a transmembrane domain).

Since the reference teaches all the elements of the claims, claims 1, 3, 4 and 19 are anticipated by U.S. Patent No. 6,319,689 to Powell et al.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
25 September 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

SEQ ID NO: 3
AR178469

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LOCUS       AR178469                2541 bp    DNA     linear   PAT 20-APR-2002
DEFINITION  Sequence 1 from patent US 6319689.
ACCESSION   AR178469
VERSION     AR178469.1  GI:20219607
KEYWORDS    .
SOURCE      Unknown.
  ORGANISM  Unknown.
            Unclassified.
REFERENCE   1  (bases 1 to 2541)
  AUTHORS   Powell,D.J., Chapman,C.G., Murphy,K. and Smith,T.S.
  TITLE     ASP2
  JOURNAL   Patent: US 6319689-A 1 20-NOV-2001;
FEATURES             Location/Qualifiers
     source          1. .2541
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                     /mol_type="unassigned DNA"
ORIGIN

  Query Match             98.2%;  Score 2033.6;  DB 2;  Length 2541;
  Best Local Similarity   99.5%;  Pred. No. 0;
  Matches 2050;  Conservative    0;  Mismatches    9;  Indels    1;  Gaps    1;

Qy          1 ATGGCCCAAGCCCTGCCCTGGCTCCTGCTGTGGATGGGCGCGGGAGTGCTGCCTGCCCAC 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy         61 GGCACCCAGCACGGCATCCGGCTGCCCCTGCGCAGCGGCCTGGGGGGCGCCCCCCTGGGG 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        241 GTGGGCAGCCCCCCCGCAGACGCTCAACATCCTGGTGGATACAGGCAGCAGTAACTTTGCA 300
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Qy        421 CTGGGCACCGACCTGGTAAGCATCCCCCATGGCCCCAACGTCACTGTGCGTGCCAACATT 480
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Qy        481 GCTGCCATCACTGAATCAGACAAGTTCTTCATCAACGGCTCCAACTGGGAAGGCATCCTG 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 GCTGCCATCACTGAATCAGACAAGTTCTTCATCAACGGCTCCAACTGGGAAGGCATCCTG 540

Qy        541 GGGCTGGCCTATGCTGAGATTGCCAGGCCTGACGACTCCCTGGAGCCTTTCTTTGACTCT 600
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 GGGCTGGCCTATGCTGAGATTGCCAGGCCTGACGACTCCCTGGAGCCTTTCTTTGACTCT 600

Qy        601 CTGGTAAAGCAGACCCACGTTCCCAACCTCTTCTCCCTGCAGCTTTGTGGTGCTGGCTTC 660
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        601 CTGGTAAAGCAGACCCACGTTCCCAACCTCTTCTCCCTGCAGCTTTGTGGTGCTGGCTTC 660
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Qy        661 CCCCTCAACCAGTCTGAAGTGCTGGCCTCTGTCGGAGGGAGCATGATCATTGGAGGTATC 720
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        661 CCCCTCAACCAGTCTGAAGTGCTGGCCTCTGTCGGAGGGAGCATGATCATTGGAGGTATC 720

Qy        721 GACCACTCGCTGTACACAGGCAGTCTCTGGTATACACCCATCCGGCGGGAGTGGTATTAT 780
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        721 GACCACTCGCTGTACACAGGCAGTCTCTGGTATACACCCATCCGGCGGGAGTGGTATTAT 780

Qy        781 GAGGTCATCATTGTGCGGGTGGAGATCAATGGACAGGATCTGAAAATGGACTGCAAGGAG 840
              ||||| ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        781 GAGGTGATCATTGTGCGGGTGGAGATCAATGGACAGGATCTGAAAATGGACTGCAAGGAG 840

Qy        841 TACAACTATGACAAGAGCATTGTGGACAGTGGCACCACCAACCTTCGTTTGCCCAAGAAA 900
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        841 TACAACTATGACAAGAGCATTGTGGACAGTGGCACCACCAACCTTCGTTTGCCCAAGAAA 900

Qy        901 GTGTTTGAAGCTGCAGTCAAATCCATCAAGGCAGCCTCCTCCACGGAGAAGTTCCCTGAT 960
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        901 GTGTTTGAAGCTGCAGTCAAATCCATCAAGGCAGCCTCCTCCACGGAGAAGTTCCCTGAT 960

Qy        961 GGTTTCTGGCTAGGAGAGCAGCTGGTGTGCTGGCAAGCAGGCACCACCCCTTGGAACATT 1020
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        961 GGTTTCTGGCTAGGAGAGCAGCTGGTGTGCTGGCAAGCAGGCACCACCCCTTGGAACATT 1020

Qy       1021 TTCCCAGTCATCTCACTCTACCTAATGGGTGAGGTTACCAACCAGTCCTTCCGCATCACC 1080
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1021 TTCCCAGTCATCTCACTCTACCTAATGGGTGAGGTTACCAACCAGTCCTTCCGCATCACC 1080

Qy       1081 ATCCTTCCGCAGCAATACCTGCGGCCAGTGGAAGATGTGGCCACGTCCCAAGACGACTGT 1140
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1081 ATCCTTCCGCAGCAATACCTGCGGCCAGTGGAAGATGTGGCCACGTCCCAAGACGACTGT 1140

Qy       1141 TACAAGTTTGCCATCTCACAGTCATCCACGGGCACTGTTATGGGAGCTGTTATCATGGAG 1200
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1141 TACAAGTTTGCCATCTCACAGTCATCCACGGGCACTGTTATGGGAGCTGTTATCATGGAG 1200

Qy       1201 GGCTTCTACGTTGTCTTTGATCGGGCCCGAAAACGAATTGGCTTTGCTGTCAGCGCTTGC 1260
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1201 GGCTTCTACGTTGTCTTTGATCGGGCCCGAAAACGAATTGGCTTTGCTGTCAGCGCTTGC 1260

Qy       1261 CATGTGCACGATGAGTTCAGGACGGCAGCGGTGGAAGGCCCTTTTGTCACCTTGGACATG 1320
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1261 CATGTGCACGATGAGTTCAGGACGGCAGCGGTGGAAGGCCCTTTTGTCACCTTGGACATG 1320

Qy       1321 GAAGACTGTGGCTACAACATTCCACAGACAGATGAGTCAACCCTCATGACCATAGCCTAT 1380
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1321 GAAGACTGTGGCTACAACATTCCACAGACAGATGAGTCAACCCTCATGACCATAGCCTAT 1380

Qy       1381 GTCATGGCTGCCATCTGCGCCCTCTTCATGCTGCCACTCTGCCTCATGGTGTGTCAGTGG 1440
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1381 GTCATGGCTGCCATCTGCGCCCTCTTCATGCTGCCACTCTGCCTCATGGTGTGTCAGTGG 1440

Qy       1441 CGCTGCCTCCGCTGCCTGCGCCAGCAGCATGATGACTTTGCTGATGACATCTCCCTGCTG 1500
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1441 CGCTGCCTCCGCTGCCTGCGCCAGCAGCATGATGACTTTGCTGATGACATCTCCCTGCTG 1500

Qy       1501 AAGTGAGGAGGCCCATGGGCAGAAGATAGAGATTCCCCT-GGACCACACCTCCGTGGTTC 1559
              |||||||||||||||||| |||||||||||||||| |||||||||||||||||||||
Db       1501 AAGTGAGGAGGCCCATGGGAGAAAGATAGAGATTCCCCTGGGACCACACCTCCGTGGTTC 1560

Qy       1560 ACTTTGGTCACAAGTAGGAGACACAGATGGCACCTGTGGCCAGAGCACCTCAGGACCCTC 1619
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1561 ACTTTGGTCACAAGTAGGAGACACAGATGGCACCTGTGGCCAGAGCACCTCAGGACCCTC 1620

Qy       1620 CCCACCCACCAAATGCCTCTGCCTTGATGGAGAAGGAAAAGGCTGGCAAGGTGGGTTCCA 1679
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1621 CCCACCCACCAAATGCCTCTGCCTTGATGGAGAAGGAAAAGGCTGGCAAGGTGGGTTCCA 1680

Qy       1680 GGGACTGTACCTGTAGGAAACAGAAAAGAGAAGAAAGAAGCACTCTGCTGGCGGGAATAC 1739
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1681 GGGACTGTACCTGTAGGAAACAGAAAAGAGAAGAAAGAAGCACTCTGCTGGCGGGAATAC 1740
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Qy       1740 TCTTGGTCACCTCAAATTTAAGTCGGGAAATTCTGCTGCTTGAAACTTCAGCCCTGAACC 1799
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1741 TCTTGGTCACCTCAAATTTAAGTCGGGAAATTCTGCTGCTTGAAACTTCAGCCCTGAACC 1800

Qy       1800 TTTGTCCACCATTCCTTTAAATTCTCCAACCCAAAGTATTCTTCTTTTCTTAGTTTCAGA 1859
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1801 TTTGTCCACCATTCCTTTAAATTCTCCAACCCAAAGTATTCTTCTTTTCTTAGTTTCAGA 1860

Qy       1860 AGTACTGGCATCACACGCAGGTTACCTTGGCGTGTGTCCCTGTGGTACCCTGGCAGAGAA 1919
             |||||||||||||||||||||||||||||||||||||||||||||||||| |||||||||
Db       1861 AGTACTGGCATCACACGCAGGTTACCTTGGCGTGTGTCCCTGTGGTACCCGGGCAGAGAA 1920

Qy       1920 GAGACCAAGCTTGTTTCCCTGCTGGCCAAAGTCAGTAGGAGAGGATGCACAGTTTGCTAT 1979
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1921 GAGACCAAGCTTGTTTCCCTGCTGGCCAAAGTCAGTAGGAGAGGATGCACAGTTTGCTAT 1980

Qy       1980 TTGCTTTAGAGACAGGGACTGTATAAACAAGCCTAACATTGGTGCAAAGATTGCCTCTTG 2039
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1981 TTGCTTTAGAGACAGGGACTGTATAAACAAGCCTAACATTGGTGCAAAGATTGCCTCTTG 2040

Qy       2040 AATTAAAAAAAAAAAAAAAA 2059
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Db       2041 AATTAAAAAAAAAAACTAGA 2060
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10/652,927
Sequence alignment B
SEQ ID NO: 4

RESULT 21
US-09-009-191-2
; Sequence 2, Application US/09009191
; Patent No. 6319689
; GENERAL INFORMATION:
; APPLICANT: POWELL, DAVID
; APPLICANT: CHAPMAN, CONRAD
; APPLICANT: MURPHY, KAY
; APPLICANT: SMITH, TRUDI
; TITLE OF INVENTION: ASP2
; NUMBER OF SEQUENCES: 6
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: RATNER & PRESTIA
; STREET: P.O. BOX 980
; CITY: VALLEY FORGE
; STATE: PA
; COUNTRY: USA
; ZIP: 19482
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Diskette
; COMPUTER: IBM Compatible
; OPERATING SYSTEM: DOS
; SOFTWARE: FastSEQ for Windows Version 2.0
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/09/009,191
; FILING DATE: 20-JAN-1998
; CLASSIFICATION:
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: UK 9701684.4
; FILING DATE: 28-JAN-1997
; ATTORNEY/AGENT INFORMATION:
; NAME: PRESTIA, PAUL F
; REGISTRATION NUMBER: 23,031
; REFERENCE/DOCKET NUMBER: GH-70368
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: 610-407-0700
; TELEFAX: 610-407-0701
; TELEX: 846169
; INFORMATION FOR SEQ ID NO: 2:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 501 amino acids
; TYPE: amino acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: protein
US-09-009-191-2

Query Match 99.8%; Score 2655; DB 2; Length 501;
Best Local Similarity 99.8%; Pred. No. 8.5e-274;
Matches 500; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

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Qy          1 MAQALPWLLLWMGAGVLPAHGTQHGIRLPLRSGLGGAPLGLRLPRETDEEPEEPGRRGSF 60
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Db          1 MAQALPWLLLWMGAGVLPAHGTQHGIRLPLRSGLGGAPLGLRLPRETDEEPEEPGRRGSF 60

Qy         61 VEMVDNLRGKSGQGYYVEMTVGSPPQTLNILVDTGSSNFAVGAAPHPFLHRYYQRQLSST 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 VEMVDNLRGKSGQGYYVEMTVGSPPQTLNILVDTGSSNFAVGAAPHPFLHRYYQRQLSST 120

Qy        121 YRDLRKGVYVPYTQGKWEGELGTDLVSIPHGPNVTVRANIAAITESDKFFINGSNWEGIL 180
              ||||||||| ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 YRDLRKGVYEPYTQGKWEGELGTDLVSIPHGPNVTVRANIAAITESDKFFINGSNWEGIL 180

Qy        181 GLAYAEIARPDDSLEPFFDSLVKQTHVPNLFSLQLCGAGFPLNQSEVLASVGGSMIIGGI 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 GLAYAEIARPDDSLEPFFDSLVKQTHVPNLFSLQLCGAGFPLNQSEVLASVGGSMIIGGI 240
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Qy        241 DHSLYTGSLWYTPIRREWYYEVIIVRVEINGQDLKMDCKEYNYDKSIVDSGTTNLRLPKK 300
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Db        241 DHSLYTGSLWYTPIRREWYYEVIIVRVEINGQDLKMDCKEYNYDKSIVDSGTTNLRLPKK 300

Qy        301 VFEAAVKSIKAASSTEKFPDGFWLGEQLVCWQAGTTPWNIFPVISLYLMGEVTNQSFRIT 360
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Db        301 VFEAAVKSIKAASSTEKFPDGFWLGEQLVCWQAGTTPWNIFPVISLYLMGEVTNQSFRIT 360

Qy        361 ILPQQYLRPVEDVATSQDDCYKFAISQSSTGTVMGAVIMEGFYVVFDRARKRIGFAVSAC 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 ILPQQYLRPVEDVATSQDDCYKFAISQSSTGTVMGAVIMEGFYVVFDRARKRIGFAVSAC 420

Qy        421 HVHDEFRTAAVEGPFVTLDMEDCGYNIPQTDESTLMTIAYVMAAICALFMLPLCLMVCQW 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 HVHDEFRTAAVEGPFVTLDMEDCGYNIPQTDESTLMTIAYVMAAICALFMLPLCLMVCQW 480

Qy        481 RCLRCLRQQHDDFADDISLLK 501
              |||||||||||||||||||||
Db        481 RCLRCLRQQHDDFADDISLLK 501
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